

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 01M–0478, 01M–0460, 01M–0454, 01M–0453, 01M–0452, 01M–0456, 01M–0451, 01M–0455, 01M–0578, 01M–0507, 01M–0579, 01M–0535, 01M–0462, 01M–0461, 01M–0536, 01M–0520, 01M–0439, 01M–0509, 01M–0490, 01M–0498, 01M–0479, 01M–0480, 01M–0482, 01M–0508, 01M–0522, 01M–0537, 01M–0523, 01M–0530, 01M–0531, 01M–0534, 01M–0567, 01M–0581]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency’s Dockets Management Branch.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thanh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Instead, revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on FDA's home page at <http://www.fda.gov> on the Internet, by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch, and by publishing in the **Federal Register** after each quarter a list of available safety and effectiveness summaries of approved PMAs and denials announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from October 1, 2001, through December 31, 2001. There were no denial actions during this period. The list

provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE OCTOBER 1, 2001, THROUGH DECEMBER 31, 2001

| PMA No./Docket No. | Applicant | Trade Name | Approval Date |
|--------------------------------------|---|--|--|
| P990050/01M-0478 P000020/01M-0460 | Spectrascience, Inc. C.R. Bard, Inc. | Optical Biopsy System Stinger Ablation Catheter Templink Extension Cable | November 14, 2000 November 29, 2000 |
| P990043/01M-0454 | Diasorin, Inc. | DIASORIN ETI-EBK PLUS Assay | February 8, 2001 |
| P990042/01M-0453 | Diasorin, Inc. | DIASORIN ETI-AB-AUK PLUS Assay | March 30, 2001 |
| P990041/01M-0452 | Diasorin, Inc. | DIASORIN ETI-AB-EBK PLUS Assay | March 30, 2001 |
| P990045/01M-0456 | Diasorin, Inc. | DIASORIN ETI-AB-COREK PLUS Assay | March 30, 2001 |
| P990038/01M-0451 | Diasorin, Inc. | DIASORIN ETI MAK-2 PLUS Assay | March 30, 2001 |
| P990044/01M-0455 | Diasorin, Inc. | DIASORIN ETI-CORE IGMK PLUS Assay | March 30, 2001 |
| P000040/01M-0578 | Bei Medical Systems Co., Inc. | HYDROTHERMABLATOR Endometrial Ablation System | April 20, 2001 |
| P990012/01M-0507 | Roche Diagnostics Corp. | Elecsys Hbsag Immunoassay, Elecsys Hbsag Confirmatory, and Precicontrol Hbsag | June 1, 2001 |
| P000053/01M-0579 | American Medical Systems, Inc. | AMS SPHINCTER 800 Urinary Control System | June 14, 2001 |
| P930027(S004)/01M-0535 | Diagnostic Products Corp. | Immulite PSA, Immulite Third Generation PSA, Immulite 2000 | June 19, 2001 |
| P880086(S083)/01M-0462 | St. Jude Medical, Inc. | Integrity AFX DR Model 5346 Dual Chamber Pulse Generator and Programmer Software Model 3307, V2.2a | July 11, 2001 |
| P830045(S076)/01M-0461 | St. Jude Medical, Inc. | Integrity AFX DR Model 5346 Dual Chamber Pulse | July 11, 2001 |
| P010021/01M-0536 | Ortho-Clinical Diagnostics, Inc. | Vitros Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrator | August 30, 2001 |
| P890057(S014)/01M-0520 | Sensor Medics Corp. | Model 3100b High Frequency Oscillatory Ventilator (HFOV) | September 24, 2001 |
| P000029/01M-0439 | Q-Med Ab | Deflux Injectable Gel Ren | September 24, 2001 |
| P010017/01M-0509 | Fisher Imaging Corp. | SENOSCAN Full Field Digital Mammagraphy System | September 25, 2001 |
| P980008(S005)/01M-0490 | Lasersight Technologies, Inc. | Lasersight Laserscan Lsx Excimer Laser System For Laser-Assisted In Situ Keratomileusis (LASIK) | September 28, 2001 |
| P000036/01M-0498 | Advanced Tissue Sciences | Dermagraft | September 28, 2001 |
| P010019/01M-0479 | Ciba Vision Corp. | Focus Night And Day (Lotrafalcon A) Soft Contact Lenses | October 11, 2001 |
| P000030/01M-0480 | Ciba Vision Corp. | Focus Night & Day (Lotrafalcon A) Soft Contact Lenses | October 12, 2001 |
| H010002/01M-0482 | Stryker Biotech | OP-1 Implant | October 17, 2001 |
| P000052/01M-0508 | Guidant Corp. | Galileo Intravascular Radiotherapy System | November 2, 2001 |
| P930016(S014)/01M-0522 | VISX, Inc. | VISX STAR Excimer Laser System | November 6, 2001 |
| P010007/01M-0537 | Diagnostic Products Corp. | Immulite/Immulite 2000 Afp Assays | November 9, 2001 |
| P990015/01M-0523 | Lifecore Biomedical, Inc. | Intergel Adhesion Prevention Solution | November 16, 2001 |
| P000057/01M-0530 | Ascension Orthopedics, Inc. | Ascension Mcp | November 19, 2001 |
| P980006(S004)/01M-0531 | Bausch & Lomb, Inc. | Purevision (Balafilcon A) Visibility Tinted Contact Lenses | November 20, 2001 |
| P010032/01M-0534 | Advanced Neuromodulation System, Inc. | Genesis Neurostimulation (lpg) System | November 21, 2001 |
| P010003/01M-0567 | Cryolife, Inc. | BIOGLUE Surgical Adhesive | December 3, 2001 |
| P010020/01M-0581 | American Medical Systems, Inc. | AMS Acticon Neosphincter | December 18, 2001 |

II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cdrh/pmapage.html>.

Dated: May 10, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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